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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,865	02/02/2001	Carl G. Hellerqvist	22100-0100 (46126-252687)	7056

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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/776,865	HELLERQVIST, CARL G.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2004 and 16 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-16,29-38 and 40-56* is/are pending in the application.

4a) Of the above claim(s) *49-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-16,29-38,40-48,55 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 16, 2004 has been entered.

2. The amendment filed September 16, 2003 has been entered. Claims 2, 17-28, 57, and 58 have been canceled. Claims 1, 7, 12, 14, 44, 48, and 55 have been amended.

3. Claims 1, 4-16, 29-38, and 40-56 are pending in the application. Claims 49-54 have been withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

4. Claims 1, 4-16, 29-38, 40-48, 55, and 56, insofar as the claims are drawn to elected invention, are currently under prosecution.

Grounds of Objection and Rejection Withdrawn

5. Unless specifically reiterated below, Applicant's amendment filed September 16, 2003 has obviated the grounds of objection and rejection set forth in the previous Office action mailed July 16, 2003.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 4-16, 29-38, 40-48, 55, and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For essentially the reasons set forth in section 9 of the previous Office action mailed July 16, 2003, the amount of guidance, direction, and exemplification set forth in Applicant's disclosure would not enable the skilled artisan to make and use the claimed invention without first having to perform an undue amount of additional experimentation, which falls beyond the realm of routine experimentation.

The factors that have been considered in determining whether undue experimentation is required are summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). These factors include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

As evidenced by the teachings of the references cited in the previous Office action to address the level of skill in the art and the state of the art, now and as of the earliest filing date sought by Applicant in the instant application, the art is characterized by a high level of complexity, as well as unpredictability. Upon considering the nature of the invention and the breadth of the claims, it appears that the amount of guidance, direction, and exemplification set forth by Applicant is not reasonably commensurate in scope with the claims. Therefore, although the relative skill of those in the art is high, absent a sufficient disclosure to enable the use of the claimed invention, an undue amount of additional experimentation, that is, beyond the realm of routine

experimentation, would have to be performed before the claimed invention, commensurate in scope with the claims, could be made and used.

In conclusion, upon careful consideration of the factors used to determine whether undue experimentation is required, in accordance with *Ex parte Forman*, 230 USPQ 546 (BPAI 1986), the amount of guidance, direction, and exemplification disclosed by Applicant is not deemed sufficient to enable the skilled artisan to use the claimed invention without a need to perform an undue amount of additional experimentation.

At pages 14-17 of the amendment filed September 16, 2003, Applicant has traversed the grounds of rejection set forth under 35 USC § 112, first paragraph in the previous Office action. Briefly, Applicant has argued that while the Office has cited references that are generally applicable to the question of whether Applicant's disclosure would be sufficiently enabling, as required by 35 USC § 112, first paragraph, the Office has not provided any factual evidence showing that the particularly claimed invention is not sufficiently enabled by Applicant's disclosure. Applicant has further argued that the skilled artisan is aware that animal models, such as mice provide data that has been extrapolated to accurately predict the outcome of similar treatments in humans; and accordingly, Applicant has respectfully that Applicant is not required to provide factual evidence that the invention can be used to prevent cancer in humans, so long as the skilled artisan, given Applicant's disclosure, would find the assertion probable.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

First, regarding Applicant's submission that human testing is not required to obtain a patent, Applicant is indeed correct; however, to obtain a patent, Applicant's disclosure of the claimed invention must provide a sufficient amount of guidance, direction, and exemplification to enable the skilled artisan to make and use that invention without having to first perform an undue amount of additional and non-routine

experimentation. The preponderance of factual evidence of record shows that the art is highly unpredictable. Despite the application of animal models to predict the effectiveness of particular treatment regimens in humans, the art (e.g., Gura) teaches that the results acquired using animal models cannot be used to *reliably* predict the outcome of similar treatments in humans; in other words, the art of animal modeling to discover and develop new therapies for cancer is an unpredictable art. Gura very succinctly teaches, "xenograft tumors don't behave like naturally occurring tumors in humans" (page 1041, column 2). Although researchers had hoped that xenografts would prove to better models for studying cancer in humans and screening candidate therapeutic agents for use in treating patient diagnosed with cancer, Gura discloses, "the results of xenograft screening turned out to be not much better than those obtained with the original models". Gura states that as a result of their efforts, " '[w]e had basically discovered compounds that were good mouse drugs rather than good human drugs' " (page 1041, column 2).

In view of the preponderance of evidence, which has been made of record in established a case for the insufficiency of the specification to meet the requirements set forth under 35 USC § 112, first paragraph, it is not immediately apparent that these requirements have been met, and therefore Applicants have the burden of persuading the Office that, given only the benefit of the instant disclosure, the skilled artisan could make and use the claimed invention without having to perform an undue amount of experimentation at the time the application was filed. Notably, the situation faced by Applicants in the course of the instant prosecution is not analogous to that faced by Brana et al. (*In re Brana*, 34 USPQ2d 1436, CAFC 1995), since notably Applicant has not established the clinical utility of the claimed invention, nor have Applicants provided a reasonably correlative study suggesting the potential utility of the claimed invention. In the present regard, it is not merely a question of whether or not a favorable comparison of the claimed invention and proven effective antitumor therapeutic compounds implicitly asserts that the invention is also highly effective against cancer, or whether such a disclosure can be reasonably extrapolated to reliably predict the efficacy of the claimed invention encompassing clinical application. Again, the factors, which

have been considered in determining whether undue experimentation would be required, have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). Considering the nature of the invention, the state of the art at the time the application was filed, the level of skill in the art, the level of predictability in the art, the breadth of the claims and the amount of exemplification disclosed by Applicants, the quantity and type of experimentation that would be required before the claimed invention might be practiced with a reasonable expectation of success in view of such factors is considered undue. In contrast to the situation faced by Brana et al., in order to practice the claimed invention in this instance, the skilled artisan would not merely be required to perform routine experimentation using conventional methodology to determine optimally safe and effective dosages and schedules for administration. Contrary to the situation faced by Brana et al., in this instance, there does not appear to be a reasonable presumption of the utility of the claimed invention.

Secondly, regarding Applicant's argument that the Office has not provided any factual evidence showing that the particularly claimed invention is not sufficiently enabled by Applicant's disclosure, Applicant is correct. In order to address this deficiency, it is aptly noted herein that Fu et al. (*Clinical Cancer Research* **7**: 4182-4194, 2001) provides factual evidence that the particularly claimed invention cannot be used to prevent cancer in mice; see the entire document, particularly Figure 6 at page 4192. Fu et al. vaccinated mice with HP59- and SP55-derived peptides and found that, while tumor growth was attenuated in the immunized mice, as compared that in to non-immunized mice, the immunization was not effective to prevent cancer (page 4192, Figure 6). As the present claims are drawn to a method for preventing cancer, because Fu et al. shows that the claimed invention cannot be used to prevent cancer, it is apparent that the claimed invention cannot be enabled by Applicant's disclosure.

In view of Fu et al. and the other references cited to show the general state of the art and to characterize its high level of unpredictability, in the absence of exemplification that is reasonably commensurate in scope with claims, the skilled artisan could not make and use the claimed invention without having to first perform an undue amount of experimentation to discover which embodiments of the claimed invention can be made

and used to prevent cancer in a mammal and more particularly in a human. In deciding *In re Fisher*, 1666 USPQ 19 24 (CCPA 1970), the Court indicated the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. It has been well known to those skilled in the art at the time the invention was made that minor structural differences among structurally related compounds or compositions could result in substantially different biological and pharmacological activities. The specification does not teach the skilled artisan to make any other substances, which can be used to practice the claimed invention; and the skilled artisan cannot predict whether any given substance can be used to successfully practice the claimed invention. Defining a substance by its principal biological activity amounts to an alleged conception having no more specificity than that of a wish to know the identity of any material with that biological property. See *Colbert v. Lofdahl*, 21 USPQ2d, 1068, 1071 (BPAI 1992). Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Therefore, the claims would merely serve as an invitation to one skilled in the art to identify a substance having the ability to prevent and/or treat cancer.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
July 21, 2004

Jeffrey Siew
SUPERVISORY PATENT
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TC 1600
7/23/04